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The Tuberculin Skin Test (TST)

Policy: The TST is one of the current testing methods utilized in Missouri to detect individuals who may have been infected with Mycobacterium Tuberculosis.

Purpose: To provide basic information concerning the tuberculin skin test.

1. The TST detects individuals infected with M. Tuberculosis.

2. The skin test is administered intradermally using the Mantoux technique by injecting 0.1 ml of 5 TU (tuberculin unit) purified protein derivative (PPD) solution.
   a. PPD is available in various strengths, containing one (1) tuberculin unit (TU), 5 TU, and 250 TU.
   b. Only 5 TU is routinely used in public health and is the only strength PPD addressed in this manual.

3. If a person is infected, a delayed type hypersensitivity reaction is detectable 2-10 weeks after infection.

4. Interpretation of TST reactions should be conducted within 48-72 hours after administration by a trained health care professional.
   a. If the test is not read within the 48-72 hours it must be repeated.
   b. Patients or family members should NOT interpret or read TST results.

5. PPD is light and heat sensitive, when not in use it should be protected from light and stored in a refrigerator at 35-46° Fahrenheit.

6. While in use in the field the PPD temperature should be maintained.

7. PPD should never be transferred from one vial to another.

8. The TST should not be performed on a person who has a **documented** history of either a positive result or treatment for TB disease.

9. TB disease must be ruled out before initiating treatment for LTBI to prevent inadequate treatment of TB disease.

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Targeted Tuberculin Testing

Policy: Targeted testing programs should be conducted among groups at risk for recent infection with M. tuberculosis and those who are at increased risk for progression to active Tuberculosis (TB).

Purpose: To identify persons at high risk for TB who would benefit by treatment of LTBI.

Persons at high risk for developing TB disease fall into two broad categories:

1. **Recently Infected:**

   The risk of progression is greatest within the first 1-2 years after exposure. Persons likely to have been recently infected with M. tuberculosis include the following:

   - ❖ Close contacts of infectious contacts.
   - ❖ Recent TST converters.
     Person with baseline testing results that have an increase of 10mm or more in the size of the TST reaction within 2 years.
   - ❖ Persons who have immigrated from TB-endemic regions of the world.
   - ❖ Children < 5 years of age who have a positive TST.
   - ❖ Persons who work or reside in facilities/institutions with people who are at high risk for TB such as hospitals, homeless shelters, correctional facilities, nursing homes, residential facilities for patients with AIDS, or residential substance abuse treatment facilities.

2. **Clinical conditions associated with progression from LTBI to TB disease:**

   - ✓ HIV Infection
   - ✓ Injection drug use
   - ✓ Radiographic evidence of prior healed TB
   - ✓ Low body weight (>10% below ideal)
   - ✓ Other medical conditions:
     - ❖ Silicosis
     - ❖ Diabetes
     - ❖ Chronic renal failure or on hemodialysis
     - ❖ Gastrectomy
     - ❖ Jejunoileal bypass
     - ❖ Solid organ transplant
     - ❖ Head and neck cancer
     - ❖ Prolonged use of steroids or TNF-α antagonist

Screening of low-risk persons is discouraged because it diverts resources from activities of higher priority.

TST testing is also discouraged unless a plan has been developed to complete a course of treatment in persons found to have LTBI. This would include:

- Arrangements for medical evaluation
- Chest X-rays
- Medical supervision for a course of treatment

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Screening Foreign-Born Persons

Tuberculosis (TB) cases among foreign-born persons make up a large percentage of our total number of cases in this state. In some countries, TB is much more prevalent than it is in the United States; therefore, persons emigrating from TB endemic countries will have a higher prevalence of TB infection and disease.

STATEWIDE RECOMMENDATIONS:

Foreign-Born Students: The Department of Health & Senior Services (DHSS), TB Control Program recommends the following for the state's university and college campuses as a condition of enrollment:

1. All students and faculty should be required to have a Tuberculosis screening test.
2. All students and faculty who are put on TB medications should receive directly observed therapy through the student health center.

Foreign-Born Persons That Have Been in U.S. Less Than Five Years: Recognizing that recent arrival to the United States from TB-endemic countries is a significant risk factor for the development of TB in foreign-born individuals, it is recommended that these individuals be considered high priority for TB screening and TB infection treatment. Specifically, it is recommended that foreign-born persons (including students, immigrants, and refugees), notably those from endemic countries*, who have TB infection as evidenced by a positive tuberculin reaction and who have been in the Unites States less than five years, receive TB infection treatment, **regardless of age or BCG vaccination status.**

*Countries with high TB prevalence include those located in Asia, Africa, Latin America, Eastern Europe (including the former Soviet Union and Yugoslavian Republics), the Caribbean and Pacific Islands.

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Screening Long-Term Care Facilities

The control and prevention of tuberculosis in the elderly must be accomplished in order to eliminate tuberculosis as a public health problem.

Many of the elderly were infected with tuberculosis years ago, with the tubercle bacilli dormant most of the time. When the bacilli occasionally became active and began reproducing, the normal immune system quickly overcame the problem. As the body ages, the immune system becomes less active, and other medical problems may develop that further increase the risk of tuberculosis infection becoming active disease. If tuberculosis disease is in the lung, which is the most common site, the person may start coughing and expelling the organisms into the air. This can be especially devastating in a long-term care facility, where many susceptible elderly persons are sharing the same air.

It is therefore important for each facility to have a tuberculosis control program in place. This must include the documentation of the tuberculosis status of each resident, staff member and volunteer of each long-term care facility. This can best be accomplished by screening residents on admission, and pre-employment and annual testing of employees and volunteers as outlined below.
Missouri State Regulations: 19 CSR 20-20.100 (see the *Appendices* located at:
http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf)

Recommendations for Residents

All residents new to long-term care who do not have documentation of a previous skin test reaction ≥10 mm or a history of adequate treatment of tuberculosis infection or disease, should have the initial test of a Mantoux PPD two-step test to rule out tuberculosis within one month prior to or one week after admission. If the initial result is 0-9mm, the second test, which can be given after admission, should be given at least one week and no more than three weeks after the first test. The results of the second test should be used as the baseline. Documentation of a chest x-ray ruling out active pulmonary tuberculosis within one month prior to admission, along with an evaluation to rule out signs and symptoms of tuberculosis, may be acceptable by the facility on an interim basis until the Mantoux PPD two-step test is completed.

The two-step test is recommended due to the "booster phenomenon," which can occur at any age, but is more pronounced with increased age. The body's response to tuberculin (the antigen in PPD), once that response has been established by infection with tuberculosis (or other mycobacteria), may gradually wane over the years. The initial test of two-step test may result in a falsely negative (0 – 9 mm) reading. However, that initial test stimulates the body to respond normally to a subsequent test. This can cause confusion at a later time if the resident is skin

tested either as a result of symptoms of tuberculosis disease or as a contact to a newly diagnosed infectious person. The "boosted" skin test then may appear to be the result of new infection, which puts the individual at much higher risk of progressing to tuberculosis disease. Therefore, it is imperative to purposely elicit this boosted response deliberately in all persons in whom it is important to know their tuberculosis status.

Skin test results of ≥10 mm, whether documented in the resident's medical history, obtained by the first test, or obtained by the second of the two-step test applied by the facility, require a chest x-ray to rule out current tuberculosis disease. It is important to also perform an evaluation to determine if signs or symptoms of tuberculosis (unexplained weight loss, fever, persistent cough) are present. Once tuberculosis disease is ruled out, it is important to record the results of the skin test in millimeters (mm), in a prominent place on the resident's medical record. Including the skin test result at the same place and in the same manner as the resident's allergies is appropriate.

Anyone with tuberculosis infection may progress to infectious tuberculosis disease. Since residents will be sharing air with others who, because of their age and other medical conditions, may be more susceptible to infection with tuberculosis, consideration of a routine course of infection treatment, which kills tubercle bacilli and prevents progression to disease, is recommended. This is especially important in infected persons of any age who have an increased risk of progressing to tuberculosis disease. These include:

1. Persons with skin test reactions ≥5 mm with no symptoms of tuberculosis and no documented history of an adequate course of antituberculosis medications but with fibrotic lesions noted on chest x-ray.

2. Persons with skin test reactions ≥5 mm with HIV infection and those with risk factors associated with HIV infection whose HIV status is unknown. Preventive therapy may be considered for HIV infected persons who have skin test reactions of <5 mm in groups where the prevalence of tuberculosis is high.

3. Close contacts of persons with newly diagnosed infectious tuberculosis who have skin test reactions of ≥5 mm.

4. Recent skin test converters (≥10 mm increase within a 2 year period.) ALL children ≤4 years with a skin test reaction of ≥10 mm are included in this group.

5. Persons with skin test reactions ≥10 mm and the following medical conditions:

    a) Diabetes mellitus,
    b) Prolonged corticosteroid therapy (>15 mg of Prednisone or equivalent daily for 2-3 weeks),
    c) Immunosuppressive therapy,

d) Hematologic and reticuloendothelial diseases (i.e., leukemia or Hodgkin's disease).
e) IV drug users.
f) End stage renal disease.
g) Chronic under nutrition (i.e., intestinal bypass surgery, gastrectomy, chronic ulcer disease, chronic malabsorption syndrome, chronic alcoholism, cancer of the oropharynx and upper gastrointestinal tract).

In addition, even in the absence of any of the above risk factors, the following persons with skin test readings ≥10 mm are recommended for infection treatment:

1. Foreign-born persons from Latin America, Asia, Africa, Eastern Europe (including Russia and Bosnia), Caribbean and Pacific Islands.

2. Medically underserved low-income populations, including high-risk racial or ethnic minority populations, especially black, Hispanic, and Native Americans.

3. Residents, employees and volunteers of long-term care facilities, other health care facilities, schools and child-care facilities.

Annual skin tests for residents with documented results <10 mm are not required, nor are annual chest x-rays for residents with documented skin test results ≥10 mm. Staff persons must be constantly vigilant for signs and symptoms of tuberculosis in residents, and obtain a chest x-ray and sputum specimens should such appear.

Recommendations for Employees

The results of annual tuberculin testing of employees in a long-term care facility are a good indicator of the extent of transmission of tuberculosis within that facility. The following occupationally-exposed persons should be tested at least annually: all employees, attending physicians and dentists, volunteers who spend ≥10 hours weekly in the facility, nursing and allied health personnel, students, instructors and other individuals in regular attendance within long-term care facilities. Every facility should have a tuberculosis surveillance program that includes the following procedures:

1. Initial Examination. Provide a tuberculin skin test (Mantoux, 5 tuberculin units (TU) of purified protein derivative (PPD)) to all employees during pre-employment procedures, unless a previous reaction ≥10 mm is documented. If the initial skin test result is 0 - 9 mm, a second test should be given at least one week and no more than three weeks after the first test. The results of the second test should be used as the baseline in determining treatment and follow-up of these employees. A history of BCG (bacilli Calmette-Guerin) does not preclude an initial screening test, and a reaction of 10 mm or more should be managed as a tuberculosis infection. A chest x-ray examination should be provided for

employees who have a skin test reaction ≥10 mm or who have symptoms compatible with pulmonary tuberculosis in order to determine the presence of current disease.

2. Repeat Tuberculin Skin Tests. It is generally recommended that employees be skin tested on an annual basis as a means of surveillance within a facility. Preventive therapy is recommended for all infected employees, unless specifically contraindicated, to prevent them from developing disease and infecting others. Infected employees who are without disease and who do not complete a course of preventive therapy will need an individualized plan of surveillance. Those who are at high risk of developing disease, i.e. converters, should be assigned where they cannot expose small children, immunocompromised patients, and others for whom the consequences of infection may be especially serious.

3. Repeat Chest X-Ray. After the initial evaluation of persons with skin test reactions ≥10 mm, routine repeated chest x-rays are not recommended. They are neither a substitute for preventive therapy nor vigilance for signs and symptoms of tuberculosis disease. Employees who have completed an adequate course of treatment or preventive treatment should be exempt from further chest x-rays unless they become symptomatic.

4. Reactors with Symptoms of Tuberculosis. All persons with significant reactions to the tuberculin skin test should be instructed to seek medical attention if they have persistent symptoms of tuberculosis.

5. Contact Investigations. When there is an exposure to a suspected or recently diagnosed case of tuberculosis, a contact investigation should be conducted. Each person exposed who previously had a negative reaction to the skin test should receive a tuberculin test. Those who are still negative should be retested three months after exposure. Preventive therapy should be given to high-risk contacts with negative skin tests since they may be infected, even though their skin tests have not yet converted.

   Chest x-rays should be provided for employees whose skin test reactions increase >6 mm from <10 mm to ≥10 mm. Treatment for infection or disease should be provided according to the results of the x-ray.

6. Evaluation. The data generated from this testing should be analyzed periodically to determine and revise policies. The best index of the effectiveness of the program will be the absence of new infections in employees.

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Screening Staff and Inmates

Policy: To ensure that tuberculosis evaluation and control services are provided for residents and staff of the Missouri Department of Corrections, according to MO 19 CSR 20-20.100.

Purpose: To control tuberculosis within the Missouri Department of Corrections by early identification of those persons with infectious tuberculosis and providing appropriate isolation and anti-tuberculosis medication regimens, early identification of those with tuberculosis infection and providing infection treatment, and by rapid contact identification, investigation, evaluation and follow-up for all residents and staff of the Department.

Procedure: **Initial screening**

Staff members: Upon employment, all staff members of the Missouri Department of Corrections, including volunteers who spend 10 or more hours weekly within the system, and who do not have documentation of a tuberculin skin test reaction of ≥10 mm, will be screened for tuberculosis, using the Mantoux PPD two (2)-step tuberculin skin test or the Interferon Gamma Release Assay (IGRA). (See Chapter 3 of the ***Core Curriculum on Tuberculosis: What the Clinician Should Know*** located at*:* http://www.cdc.gov/tb/webcourses/CoreCurr/index.htm*)*. This screening may be provided at the local health unit, under contract to the Missouri Department of Corrections, or by the person's own health care provider. Documentation of the reaction to the tuberculin skin test reported in mm of induration and positive blood assay results must be presented to the tuberculosis control coordinator of the institution. **All positive results must be reported to the Department of Health and Senior Services TB Control Program on Form TBC-4 (see the *TB Manual*; *Appendices/Sample Forms* located at**: http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf).

Inmates: Upon entrance into the Department of Corrections system, all residents will be screened for tuberculosis, **using an approved TB screening test** (See Chapter 3 of ***Core Curriculum on Tuberculosis: What the Clinician Should Know*** located at*:* http://www.cdc.gov/tb/webcourses/CoreCurr/index.htm). This screening will be provided at the Department of Correction Reception Centers. Documentation of the reaction to the tuberculin skin test, reported in mm of induration, and positive blood assay results become a part of the resident's medical record.

All positive reactions to the tuberculin skin test are reported to the Department of Health and Senior Services TB Control Program on Form TBC-4 (see the *TB Manual*; *Appendices/Sample Forms* located at: http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf).

Annual Screening

Staff members: All staff members with tuberculin skin test reactions <10 mm will have an annual Mantoux PPD tuberculin skin test, (1) step only or IGRA during each employee's birth month.

Inmates: All inmates with tuberculin skin test reactions <10 mm will have an annual Mantoux PPD tuberculin skin test, (1) step only or IGRA during each inmate's birth month.

For more information on Department of Corrections Guidelines see the American Correctional Association at: https://www.aca.org/

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Information for School Nurses

For effective tuberculosis control among school employees in Missouri, the following policies are recommended:

All personnel, paid and unpaid, who work with children in any capacity shall be certified free from tuberculosis in an infectious form prior to beginning employment. This includes an evaluation **THAT** indicates no signs or symptoms of infectious tuberculosis disease (persistent cough for >3 weeks, unexplained weight loss, fever, night sweats, general malaise) **AND** one of the situations described in below:

1. An individual who has documentation of a Mantoux PPD tuberculin skin test reading of 0 – 9 mm within the past month, and no history of contact with a person with tuberculosis immediately prior or subsequent to this documentation, shall be considered to be free from tuberculosis. No further skin testing shall be necessary except for epidemiologic or diagnostic purposes which may be required by the local health unit or the Department of Health & Senior Services.

2. If the individual **DOES NO**T have documentation of a Mantoux PPD tuberculin skin test reading of 0 – 9 mm within the past month and DOES NOT have a history of ever having had a Mantoux PPD tuberculin skin test reading of 10 or more mm, the following procedures shall be followed:

    a. Five tuberculin units (TU) of purified protein derivative (PPD) shall be administered by the Mantoux method and the results read 48-72 hours subsequent to the administration of the test.

    b. If the reading shows an induration of 0 – 4 mm in a person with a recent history of contact with tuberculosis **OR** an induration of 5 – 9 mm and no history of contact with tuberculosis, he/she shall be considered to be free of tuberculosis.

    c. If the reading shows an induration of 5 – 9 mm and there is a history of contact with tuberculosis **OR** an induration of 10 or more mm, he/she shall be considered to be a tuberculin reactor and shall be handled as described in number 3 below.

3. If the individual is a tuberculin reactor as described in 2.c above OR has a history of a Mantoux PPD tuberculin skin test reading of 10 or more mm without documentation of having received an adequate course of preventive therapy, the following procedure shall be followed:

a. If the individual has documentation of a normal chest x-ray within the past month, the employee shall be considered to be free from infectious tuberculosis.

b. If the individual does not have documentation of a normal chest x-ray within the past month, a signs and symptoms review is to be completed. If the individual has symptoms consistent with tuberculosis, then a chest x-ray is necessary. Individuals, for whom no tuberculosis symptoms exist, no further chest x-rays are required but shall be considered for preventive therapy.

Individuals described in 3.a or 3.b above, for whom chest x-rays are normal, shall be considered for preventive therapy (Isoniazid for 6-12 months). No further chest x-rays are necessary, unless the employee has symptoms consistent with tuberculosis, as described in the first paragraph of this subsection.

c. Individuals with an abnormal chest x-ray indicating fibrotic lesions or "old" tuberculosis, without documentation of an adequate course of chemotherapy, shall be considered for preventive therapy.

d. Individuals with an abnormal chest x-ray indicating current pulmonary disease (tuberculosis or other) must be thoroughly evaluated and treated accordingly. Such an evaluation must include, but not be limited to collection of sputum specimens (by induction if necessary) for tuberculosis smear and culture. Until infectious tuberculosis is ruled out, the individual should not "share air" with any children, nor with any susceptible adults not already exposed.

4. If the individual has documentation of an adequate course of therapy for tuberculosis disease or adequate infection treatment for tuberculosis infection AND no current pulmonary symptoms, no further chest x-rays are necessary and the employee shall be considered to be free from tuberculosis in an infectious form.

The school should consult with the local health department or the Bureau of Communicable Disease Control and Prevention of the Missouri Department of Health & Senior Services for evaluation, management, and surveillance if the individual meets any of the following criteria:

a. Has a history of tuberculosis disease or infection without documentation of adequate treatment as determined by the Unit.

b. Is currently being treated for tuberculosis disease.

c. Has a chest x-ray consistent with pulmonary tuberculosis without documentation of adequate treatment.

d. Has symptoms consistent with tuberculosis.

e. Has a history of contact with tuberculosis within the past 24 months.

For information on communicable diseases (see *Communicable Disease Investigation Manual* located at:
http://health.mo.gov/living/healthcondiseases/communicable/communicabledisease/cdmanual/index.php)

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Administering the TST

Policy: Tuberculin skin tests will be administered per CDC recommendations as indicated below.

Purpose: To standardize administration of the tuberculin skin test.

Equipment and Supplies:

1. Obtain order for administering TST – either individual's health care provider or per standing order for the Local Public Health Agency (LPHA).

2. Sterile 1 ml. tuberculin syringe with 27 gauge blunt beveled 1/4 - 1/2 inch needle.
   - Syringe and needle technologies continue to evolve to prevent needlestick injuries. The most effective needleless system should be used.
   - Institutional policy will determine which device had been approved by your facility.

3. Alcohol pads

4. 5TU PPD - Properly stored at 2-8° C/35-46° F; Avoid exposure to light.
   a. Tubersol and Aplisol are two commercially available tuberculin products.
      - Compared with the US reference PPD, no difference exists in TST interpretation between the two products.
      - Tuberculosis (TB) screening programs should use one antigen consistently.
   b. Avoid temperature fluctuations: do not store on the refrigerator door.

5. Cotton balls.

6. Sharps disposal container.

7. Ruler with mm indicators.

8. Signature for informed consent to be tested (The parent or guardian must sign the consent for testing, if the person to be tuberculin skin tested is <18 years of age).

9. Emergency kit and standing orders for use should an anaphylactic reaction occur (extremely rare).

Procedure for Administration of Tuberculin Skin Test:

1. Use appropriate hand hygiene before starting procedure.
2. Obtain results of all previous TSTs. Ask patient to describe what the test area looked like 2-3 days after administration: obtain documentation.
    a. If documentation cannot be obtained you may repeat the TST.
    b. A previous positive TST is not a contraindication to a subsequent TST unless the test was associated with a severe ulceration or anaphylactic shock.
3. Explain the procedure to the individual:
    a. How the test is administered.
    b. The need for reading the skin test in 48-72 hours.
    c. Make an appointment for the patient to return:
        - If the patient cannot return within 48-72 hours, do not administer the test.
        - Schedule another time that allows for the patient to return at the appropriate time.
4. Remove the antigen vial from the refrigerator and confirm that it is the 5 TU PPD antigen.
5. Check label and expiration date.
6. Mark opening date and initials on vial. If vial has reached expiration or is greater than 30 days since opened, vial should be discarded.
7. Clean vial stopper with antiseptic swab.
8. Twist needle guard on syringe to ensure tight fit.
9. Fill syringe immediately after vial is removed from refrigeration.
10. Syringes should be filled immediately prior to administration as the PPD can adhere to the inside of the syringe and affect the potency.
11. Insert needle into vial.
12. Draw slightly over 0.1ml of 5 TU PPD into syringe.
13. Remove excess volume or air bubbles to exactly 0.1ml of 5 TU PPD while needle remains in vial to avoid wasting of antigen.
14. Remove needle from vial.
15. Return antigen vial to refrigerator immediately after filling.

Site Selection and Cleaning:

1. Select upper third of forearm with palm up >2 inches from wrist, elbow, or other injection site; if neither arm is available or acceptable for testing, the back of the shoulder is a good alternate site for testing.
    a. Select site free from veins, lesions, heavy hair, bruises, scars or muscle ridges.
    b. Traditionally the left arm is used for testing; or standard site for your institution.
2. Clean arm site with antiseptic swab using a circular motion from center to outside.
    a. Allow site to dry before administering antigen.

TST Administration:

1. Rest patient arm on firm, well-lit surface.
2. Stretch taut the skin between the thumb and forefinger or pull skin taut from under the arm.
3. Hold needle bevel up at 5-15 degree angle to skin.
4. Insert needle in first layer of skin with tip visible beneath the skin.
5. Advance needle until entire bevel is under the first layer of skin.
6. Release stretched skin.
7. Inject entire dose slowly.
8. Form 6-10mm wheal.
9. Remove needle without pressing on area – do not apply band-aid.
10. Activate safety feature of device per manufacturer's recommendations, if applicable.
11. Immediately place used needle and syringe in sharps container; do not recap needle; or if necessary to recap needle, use one handed recapping technique to avoid needlestick injuries.
12. A 6-10mm wheal (a pale, raised area with distinct edges) should appear (measure with mm ruler).
13. If a 6-10mm wheal was not achieved, repeat TST. Apply the second TST on the other arm or in a different area on the same arm at least 2 inches from first site.
14. If blood or fluid is present, blot slightly with gauze or cotton ball, do not apply band-aid.
15. Record the date, time, location, antigen, and signature of person administering the TST on the TBC-4 or other form per LPHA policy.
16. Use appropriate hand hygiene after placing TST.

Care Instructions for Injection Site:

1. The wheal (bump) is normal and will remain for about 10 minutes.
2. Do not touch the wheal; avoid scratching.
3. Avoid pressure or bandage on injection site.
4. Rare local discomfort and irritation does not require treatment.
5. May wash with soap and water after about 1 hour.
6. No lotions or liquids on site, except for light washing, as mentioned above.
7. Keep appointment for reading.

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Reading the TST

Policy: Tuberculin skin tests will be read as outlined below.

Purpose: To provide standardization of reading of tuberculin skin test.

Preliminary:

1. Use appropriate hand hygiene methods before starting and put on gloves.
2. Keep fingernails shorter than fingertips to avoid misreading TST result.
3. Keep TST reading materials at hand – ballpoint pen and ruler.
4. Inspect the site of injection.

Palpate:

1. Palpate with arm bent at elbow.
2. Lightly sweep 2 inch diameter from injection site in four directions.
3. Use zigzag featherlike touch.

Placing marks: (If induration present)

1. Use fingertips to find margins of the induration; when palpating for margins, be careful not to confuse a margin of induration with a margin of muscle. To check this, raise the patient's arm to a 45 degree angle and palpate again. You should still be able to palpate induration.
2. Mark the induration by placing small dots on both sides of the induration.
3. Inspect dots, repeat finger movements toward indurated margin, and adjust dots if needed.
4. Verify the positive TST by having a second reader immediately measure the same TST using the same procedure to confirm TST.
5. Mark dots transverse (perpendicular) to long axis of forearm i.e. the direction in which a watchband would lie across the arm.

Placing and Reading Ruler:

1. Place the "0" marking on the ruler inside the edge of the left dot. Read the ruler line inside the right dot edge. Use lower reading if between two gradations on mm scale.
2. Use appropriate hand hygiene methods after reading the TST.

NOTE: In rare instances the reaction might be severe: vesiculation, ulceration, or necrosis of the skin. Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088 Fax: 800-FDA-0178; http://www.fda.gov/medwatch.

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Classification of TST Reactions

Policy: Results of tuberculin skin tests will be classified according to the following criteria.

Purpose: To standardize classification of tuberculin skin test results.

A reaction of five (5) or more millimeters of induration is considered positive in:

1. HIV-infected person.
2. Recent contact of infectious Tuberculosis (TB) case.
3. Persons with fibrotic changes on chest x-ray consistent with prior TB.
4. Organ transplant recipients.
5. Those who are immunosuppressed for other reasons:
    a. Taking equivalent of 15mg/day or greater of prednisone for 1 month or more.
    b. Taking Tumor Necrosis Factor – Alpha (TNF-x antagonists) i.e. Remicade, Enbrel, Humira, etc.

A reaction of ten (10) or more millimeters of induration is considered positive in:

1. Recent immigrants (within last 5 years) from high prevalence countries (Regardless of a history of vaccination with BCG).
2. Injecting drug users.
3. Residents, employees, and volunteers of high risk congregate settings (correctional facilities, long-term care facilities, hospitals and other healthcare facilities, residential facilities for patients with AIDS and homeless shelters).
4. Mycobacteriology laboratory personnel.
5. Persons with certain high risk clinical conditions.
6. Infants, children and adolescents exposed to adults at high risk for TB disease.
7. Children younger than 4 years of age.

A reaction of fifteen (15) or more millimeters of induration is considered positive in:

- Persons with no risk factors.
  Note: Routine testing is not recommended for populations at low risk for LTBI.

Skin test conversion:

- For persons with negative TST reactions that undergo repeat TB skin testing (such as health care workers), an increase in reaction size of 10 or greater within a period of 2 years should be considered a skin test conversion indicative of recent infection with M. Tuberculosis.

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Interferon Gamma Release Assay (IGRA)

Policy: The IGRA is one method currently available for determining exposure to TB. The Missouri State Public Health Laboratory does not offer IGRA testing.

Purpose: To inform the Local Public Health Agency (LPHA) of all testing methods available for diagnosing LTBI.

1. The Quantiferon TB tests are blood tests that measure a person's immune reactivity to M. Tuberculosis. Blood specimens are mixed with antigens and incubated for 16-24 hours.
2. In a person with LTBI, the blood cells recognize the tuberculin antigen and release interferon-gamma; results are based on the proportion of interferon gamma released.
3. The Quantiferon TB test was approved by the US Food and Drug Administration (FDA) in 2001. The second-generation test – Quantiferon – Gold was approved by the FDA in 2005. Quantiferon-TB Gold In-Tube was approved by the FDA in 2007. For more information see website at: http://www.cellestis.com/IRM/Content/aust/qtfproducts_tbgoldintube.html
4. Guidelines for Using the Quantiferon-TB Gold Test for Detecting Mycobacterium Tuberculosis Infection are found at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a4.htm?s_cid=rr5415a4_e
5. To locate a Quantiferon testing site see the following website at: http://www.quantiferon.com/contacts_usca.php

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Diagnosing of LTBI

Policy: To correctly diagnose and offer treatment for individuals classified as a positive diagnostic test.

Purpose: To rule out Tuberculosis (TB) disease before treatment for LTBI is initiated; failure to rule out TB disease may result in inadequate treatment and development of drug resistance.

For persons with a diagnostic test classified as **positive** (see classification of Tuberculosis Skin Test (TST) or those with negative diagnostic test that have symptoms suggestive of TB disease.

1. **Obtain a chest x-ray (CXR) as soon as possible:** A chest x-ray helps to differentiate between LTBI and TB disease in persons with positive results.
    a. The following guidelines are recommended:
        - A CXR is indicated in the absence of a positive result when a person is a close contact of an infectious TB case and treatment will be started for LTBI (window prophylaxis in a young child or immunocompromised person).
        - Children less than 5 years of age should have both an anterior-posterior and lateral views.
        - All others should have at least posterior-anterior views.
        - Other views or additional studies should be based on the physician's judgment.
        - Persons with nodular or fibrotic lesions are consistent with old TB and are high-priority candidates for treatment.
        - Persons with calcified granulomas only are low risk for progression to disease.
        - Periodic follow-up CXRs are not indicated regardless of whether treatment is completed except in unusual circumstances.
    b. Contacts to patients with Multidrug-Resistant Tuberculosis (MDR – TB).
2. A physical examination and medical history, including symptoms of tuberculosis, prior positive TSTs, family history and risk assessment for liver disease, should be conducted. Written documentation of a previous positive TST is required. A patient's verbal history is not adequate.
3. Sputum examination is indicated for persons with a positive result and either an abnormal CXR or the presence of respiratory symptoms (even if CXR is normal). If TB disease has been ruled out by the above procedures, consideration of treatment for LTBI should be considered.

For details on the *Diagnostic Services Program,* see the *TB Manual* located at:
http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Chap6.pdf)

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Two-Step Testing

Policy: Two-step tests are needed to establish a baseline for persons who will receive serial testing.

Purpose: To prevent misclassifying a positive skin test as a conversion.

Booster Phenomenon:

Some people with LTBI may have a negative reaction to the Tuberculosis Skin Test (TST) if many years have passed since they became infected. They may have a positive reaction to a subsequent TST because the initial test stimulates their ability to react to the test. This is commonly referred to as the "booster effect" and may incorrectly be interpreted as a skin test conversion (going from negative to positive). For this reason, the "two-step method" is recommended at the time of **initial** testing for individuals who will be tested periodically (e.g., health care workers). If the first test result in the two-step baseline testing is positive, evaluate the person for active disease. If active disease is ruled out then consider that the person has LTBI and evaluate and treat the person accordingly. If the first test result is negative, the second step of the two-step baseline testing should be repeated in 1 – 3 weeks. If the second test result is positive, evaluate the person for active disease. If active disease is ruled out then consider that the person has LTBI and evaluate and treat the person accordingly. However, if both steps are negative, consider the person uninfected and classify the TST as a negative baseline (see Figure 1).

To estimate the frequency of boosting in a particular setting, a four-appointment schedule of TST administration and reading (appointment for TST reading and administration of both TST results) is necessary, rather than the three-appointment schedule (appointment for the administration of both tests and reading of the second-step test only).

Two-step testing should be used only for baseline screening, not in contact investigations. In a contact investigation, for persons with a negative TST, a follow-up test should be administered 8-10 weeks after the end of the exposure (rather than 1-3 weeks later, as in two-step testing). In this instance, a change from negative to positive TST result suggests that recent exposure; transmission and infection occurred and should not be interpreted as a booster response. For more information see http://www.cdc.gov/tb/publications/LTBI/diagnosis.htm#7.

Figure 1: Two-Step Tuberculin Skin Test (TST) Method

1st TST	Negative →	Repeat TST in 1–3 weeks.
2nd TST	Negative →	Person probably does not have infection.
	Positive →	Boosted reaction due to infection in the past.

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Special Considerations in Testing for LTBI

Policy: All persons will receive testing for LTBI if indicated.

Purpose: To be aware of special conditions while testing for LTBI.

Bacille Calmette-Guerin (BCG) Vaccine:

BCG vaccine is currently used in many parts of the world where Tuberculosis (TB) is common to protect infants and young children from serious, life-threatening disease, specifically miliary TB and TB meningitis. The WHO (World Health Organization) recommends BCG vaccine once in infancy in TB endemic countries.

The question of the effect of BCG vaccine on Tuberculosis Skin Test (TST) results often causes confusion. TST reactivity caused by BCG vaccine generally wanes with the passage of time, but periodic skin testing may prolong (boost) reactivity in vaccinated persons. There is no reliable method for distinguishing between vaccine-related reactions and reactions caused by mycobacterial infections. However, the Interferon Gamma Release Assay (IGRA) tests, which use M. tuberculosis specific antigens, are designed to not cross react with BCG and may cause less false positive reactions in BCG-vaccinated individuals.

A history of BCG vaccine is not a contraindication for tuberculin skin testing or treatment for LTBI in persons with positive TST results. TST reactions should be interpreted regardless of BCG vaccination history.

HIV Infection:

The risk of progression from LTBI to TB disease is 7% to 10% EACH YEAR for those with both LTBI and Human Immunodeficiency Virus (HIV) infection. Those with LTBI and who are HIV-negative only have a 10% risk over their lifetime. HIV-infected persons may have a compromised ability to react to the TST, but should be tested for LTBI as soon as their HIV status becomes known. A negative TST reaction does not rule out LTBI. Annual repeat TST should be considered for HIV-infected persons who are TST-negative on initial evaluation.

The usefulness of anergy testing has not been demonstrated and is not recommended.

Contacts to TB Cases:

- For contacts of an infectious TB case, retesting in 8-10 weeks is indicated when the initial TST result is negative.

- Children under the age of 5 years and immunosuppressed persons who have a negative TST result should be treated (window prophylaxis) and another TST performed 8-10 weeks after contact has ended.
- If a repeat TST result is positive, treatment should be continued. If a repeat TST is negative, treatment can be discontinued. For HIV positive persons, it may be indicated to treat for LTBI even with a negative TST.
- The second test is needed in case infection occurred but was too early in onset at the time of the test.

Pregnancy:

- The TST has no adverse effects on the pregnant mother or fetus.
- If a TST is positive, obtain a chest radiograph using proper shielding.
- Consider delay of treatment 2-3 months post-partum unless higher risk (HIV- infected or recent contact) as there is increased risk of hepatotoxicity during pregnancy and the post-partum period.

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Diagnostic Services Program

Policy: To provide a medical evaluation for individuals without financial access that have been identified as infected with or suspected of having tuberculosis (TB).

Purpose: To ensure that all individuals have access to medical services to rule out active TB disease.

Procedure:

1. The patient is identified by the Local Public Health Agency (LPHA) as being tuberculin skin test positive or is suspected of having active tuberculosis:
    a. Has no medical insurance
    b. Is not eligible for Medicare
    c. Is not eligible for Veterans Affairs (VA) benefits
    d. Has no other means to pay
2. A physician is chosen from the list of DSP Providers.
3. The LPHA completes the Client Eligibility/Authorization Form **(see the *TB Manual; Appendices/ Sample Forms* located at:** http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf **)** indicating the type of service(s) requested from the list below, and faxes it to: (573) 526–0234 or 0235. The available services are:
    - First Office Visit (99205)
    - Subsequent Office Visits (99215)
    - Chest X-Ray (71020)
    - Chest X-Ray Interpretation (71020A)
    - Induced Sputum Collection (89350)

NOTE: Diagnostic services CANNOT pay for Computerized Axil Tomography (CAT or CT) scans. The DSP Program will only pay for Liver Function Tests (LFT's) on a case by case basis, with prior approval by the Department of Health and Senior Services (DHSS) TB Control Program.

4. DHSS will review for eligibility and assign an authorization number and services authorized. **For more details on *DSP Program*, see the *TB Manual* located at:** http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Chap6.pdf
5. DHSS will fax the authorization form back to the LPHA.
6. The LPHA contacts the DSP Provider and schedules the appointment. An authorization number **MUST** be obtained prior to scheduling the appointment.
7. The DSP Provider invoices DHSS directly.

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Anergy Testing

Policy: Anergy testing in conjunction with a Tuberculin Skin Test (TST) is not recommended.

Purpose: To discourage the use of anergy testing when administering TSTs.

1. Anergy testing is a diagnostic procedure used to obtain information regarding the competence of the cellular immune system.

2. The use of anergy testing in conjunction with TST is no longer recommended routinely for screening programs for M. Tuberculosis infection conducted among HIV-infected persons in the United States.

3. For more information go to:
   http://www.cdc.gov/mmwr/PDF/rr/rr4615.pdf

Annual Statement for Tuberculin Reactors Form: **(see *TB Manual; Appendices/Sample Forms* located at:**
http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf)

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